Continue Marketing Both NAMENDA® TABLETS and Once-Daily NAMENDA XR® Into the Fall of 2014 (DX371) (June 10, 2014).

99. In June 2014, in light of manufacturing issues affecting the yield of production batches of Namenda XR, higher than expected demand, and other factors, Forest announced that it would continue selling Namenda IR tablets through Fall 2014. Press Release, Forest Labs., Forest Laboratories Announces Intention to Continue Marketing Both NAMENDA TABLETS and Once-Daily NAMENDA XR® Into the Fall of 2014 (DX371) (June 10, 2014); see Stewart Decl. (DX717) ¶ 10; Meury Decl. (DX720) ¶¶ 22-23.

100. Following improvements to the XR manufacturing process, Forest regained the ability to supply the market. Stewart Dep. (CD Ex. 37) 87:6-23; Stewart Decl. (DX717) ¶ 13. On November 5, 2014, in the Actavis 3rd Quarter Earnings Press Release the company confirmed: "The Company continues to enhance manufacturing efficiencies related to its once-daily dosing of Namenda XR, and is now producing product at capacities sufficient to support transitioning all Namenda IR twice daily tablet patients to its Namenda XR® once-daily product." See Press Release, Actavis Net Revenue Increases 83% to $3.7 Billion

in Third Quarter 2014; Non-GAAP EPS Increases 53% to $3.19 (Nov. 5, 2014).

B. Distribution through Foundation Care

101. Forest actively considered alternative plans to outright discontinuance of IR, including after the State began investigating the planned withdrawal in February 2014. According to Meury, Forest's plan for limited distribution was "on the table" in February 2014 when Forest announced its plan to discontinue Namenda IR as of August 15, 2014; he also testified that it was still "on the table" when Forest announced in June 2014 that the August date was extended to the Fall. Tr. 615:1-14 (Meury). However, neither the February nor June announcements mentioned any alternative plan. See Pill Burden in Hypertensive Patients Treated with Single-Pill Combination Therapy: An Observational Study (PX34); Press Release, Forest Labs., Inc., "Forest Laboratories Announces Intention to Continue Marketing both NAMENDA® Tablets and Once-Daily NAMENDA XR® into the Fall of 2014" (PX41) (June 10, 2014).

102. Forest began speaking with Foundation Care LLC ("Foundation Care") about a limited distribution plan [redacted]

[redacted]. Tr. 616:21-25. Established in 2004, Foundation Care is accredited by the Accreditation Commission for Health Care (ACHC) as a specialty pharmacy and by National Association of Boards of Pharmacy as a Verified-Accredited Wholesale Distributor (VAWD) through July 22, 2017. Master Service Agreement ("MSA") (DX607); Foundation Care Verified-Accredited Wholesale Distributors Accreditation (DX97). It is also recorded with the New York State Board of Pharmacy as a Non-Resident Establishment Registered Wholesaler of Drugs and/or Devices, valid through May 2017, DX101-DX103, and holds a controlled substance license from the New York Department of Health, valid through November 2015, N.Y. State Dept. of Health Controlled Substance License (DX99). Foundation Care is a "full-service retail pharmacy, so any product that's available from any store in the country can be made available through Foundation Care." Blakeley Dep. 17:18-24, 38:15-18 (CD Ex. 45). Foundation Care provides reimbursement coverage for most all commercial health care plans as well as Medicaid (Pharmacy and DEME) and Medicare (Part B & D). Foundation Care Overview and Capabilities Presentation (DX87) (Oct. 21, 2014).

103. [redacted], after the State filed its initial complaint in this action, Defendants signed a Master

Services Agreement ("MSA") and Work Order with Foundation Care, to distribute Namenda IR tablets directly to patients whose physician decides it is medically necessary. MSA (DX88) [redacted]; Blakeley Dep. 46:1-6, 29:13-15. On November 5, 2014, Forest publicly announced its distribution arrangement with Foundation Care ("limited distribution"). Press Release, Actavis, Actavis Net Revenue Increases 83% to $3.7 Billion in Third Quarter 2014; Non-GAAP EPS Increases 53% to $3.19 (DX721) (Nov. 11, 2014); Kane Hr'g 500:22-501:2.

104. Under the MSA, Defendants remain the sole supplier, or "vendor," and Foundation Care becomes the sole distributor, [redacted] of IR tablets. See MSA (DX88) [redacted]. Foundation Care will ship the Namenda IR tablets within two business days of receipt of a valid prescription and Medical Necessity Order Form [redacted] MSA, Work Order No. 1 § 2.7(a) (DX88); see also Stitt Hr'g 129:12-14.

105. Foundation Care is expected to dispense Namenda IR tablets to patients on the basis of a prescription and a

Medical Necessity Form from physicians. The Work Order's Medical Necessity Form requires basic information: patient information, physician information, and a prescription; as well as a physician certification that the "Namenda [IR] tablets are medically necessary." MSA, Work Order No. 1, Medical Necessity Form (DX607); Kane Dep. 295:1619 (CD Ex. 30).

106. Though there are currently "millions" of IR prescriptions in the market, Saunders Dep. 346:19-20, [redacted] Defendants' economics expert agrees. Cremieux Dep. 91:4-15 (referring to Forest's limited distribution plan as "largely eliminating the use of that product"). Defendants predict that less than 3% of patients will take advantage of the Foundation Care program. Press Release, Actavis Net Revenue Increases 83% to $3.7 Billion in Third Quarter 2014 dated November 5, 2014 (PX501) (stating "for select groups of patients, perhaps less than 3 percent, the continued utilization of the twice-a-day tablet dosing of Namenda® might be necessary for treatment").

107. Limited distribution could impose an undue burden on physicians and their staffs, who would have to fill out more paperwork to obtain the drug for their patients, with no financial incentive to do so.

108. Like discontinuance, limited distribution would create artificial roadblocks to patient access to Namenda IR. Tr. 61:8-19 (Lah). Defendants have instructed their specialty pharmacy distributor not to dispense Namenda IR to patients unless a physician has signed a form stating that the patient has a "medical necessity" for Namenda IR. Tr. 549:2-10 (Kane). Defendants designed those roadblocks to protect their profits. Tr. 244:23-245:2 (Saunders) ("Q. The reason that you are requiring the medical necessity form is a competitive reason; it's not a medical reason, right? A. I guess you could lump it into a competitive reason.")

109. Because Namenda IR and XR are pharmacologically the same drug, doctors may not be willing to sign such a form. PX85 (Lah Decl.) ¶¶ 29-31. Dr. Lah explained the reluctance that he and other physicians may feel as follows:

> Q. Would you be uncomfortable signing this form for most of your patients even though they might, even

> though you might prefer that they continue on IR instead of switching to XR? A. Yes.

Tr. 70:14-17. He continued:

> So I'm not sure I would be comfortable continuing to prescribe Namenda IR if it were required me to declare that it was medically necessary for an individual to stay on that drug, when another perfectly good drug, Namenda XR, which may also be perfectly safe and effective may also be available for that patient.

Tr. 72:11-16 (Lah).

110. A prescription does not indicate medical necessity for Namenda IR tablets given the availability of Namenda XR:

> And so when I prescribe a medication and indicate a specific version should be dispensed, then I am indeed declaring that it is medically necessary for that individual to have that version of the drug. But as a general matter, prescribing medications in my mind does not imply that level of medical necessity.

Tr. 106:2-7 (Lah); see also Tr. 733:17-23 (Reisberg) ("Q. And I believe you testified before that you don't see a medical need for Namenda IR tablets on the market, is that correct? A. What I said was that for some of my patients, finances are a concern. At the moment—two different issues here. Yes, at the present

time, I do not—right, I do not see any—any medical need for the IR tablets, that's correct.").

111. Defendants' survey data and testimony indicate that only 2.4% of patients would be able to obtain the drug under the "medical necessity" standard, consistent with the State's contention that physicians will be reluctant to certify that Namenda IR tablets are medically necessary for their patients. Tr. 535:14-16 (Kane) ("So based on the surveys, we have quantified that approximately 2.5% or so of patients would require Namenda [IR] tablets based on medical necessity"); Kane Decl. (PX282) Ex. A; Press Release, Actavis Net Revenue Increases 83% to $3.7 Billion in Third Quarter 2014 dated November 5, 2014 (PX501) (stating "for select groups of patients, perhaps less than 3 percent, the continued utilization of the twice-a-day tablet dosing of Namenda® might be necessary for treatment.").

112. The limited distribution of Namenda IR does not materially alter the nature and impact of the earlier hard switch strategy. Tr. 336:9-337:8 (Berndt). Both discontinuance and the limited distribution are functionally hard switches.

C. The Absence of Business Purpose

113. Defendants have not established a legitimate pro-competitive justification for their plan to limit IR distribution until generic entry. Tr. 337:2-4, 411:24-412:20, 415:12-416:20 (Berndt).

114. Defendants have stated that the very purpose of the limited distribution is to blunt generic competition and prevent the operation of state generic substitution laws. Tr. 228:13-15 (Saunders) ("Q. But you intend to fight back and try to blunt the force of those laws, right? A. That's the definition of competition.").

115. According to Saunders, generic substitution laws cause the deck to be "stacked against" Defendants, and "put the thumb on the scale for the generics." Tr. 227:5-9.

> [T]he market isn't designed for generics as a standalone versus innovator. It is the innovator, the generic, the pharmacy, the PBM, the managed care company all working against the innovator. The decks are stacked incredibly the other way. That's why we refer to it as a dog fight.

Tr. 223:25-224:4.

116. Defendants have stated that the company is fighting back against the state substitution laws by seeking to convert patients from Namenda IR to Namenda XR prior to generic entry, which would allow Forest to evade the application of these laws and thus have a better chance of protecting its sales. Tr. 223:25-224:4 (Saunders); Forest Laboratories F3Q 2014 Earnings Call Transcript (PX2) (Saunders: "if we do the hard switch and we've converted patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back, at least with the existing [prescriptions]. They don't have the sales force, they don't have the capabilities to go do that. It doesn't mean that it can't happen, it just becomes very difficult. It is an obstacle that will allow us to, I think, again go into to a slow decline versus a complete cliff."). While Saunders discussed contemplated discontinuation of Namenda IR on numerous earnings calls with investors, he could never suggested that this business tactic would result in any cost savings or other efficiencies. See generally April 29, 2014 transcript of earnings call (PX366); Forest Laboratories F4Q 2014 Earnings Call Transcript (PX82); Tr. of Jan. 21, 2014 earnings call (PX2); Forest Laboratories Management Discusses Q2 2014 Results,

Earnings Call Transcript at 4 (PX485); Tr. Of Jan. 21, 2014 earnings call, annexed to Zain Decl. as Ex. 1.

117. Under a conventional scenario, i.e., leaving the older drug on the market while competing on the merits to convince physicians that the newer one is better, it would take years to convince patients and physicians to switch to Namenda XR. Tr. 694:17–20 (Hausman). The forced switch limits access to Namenda IR in order to overcome what Saunders called the "inertia" that causes most patients and physicians to resist changing medicines, with the goal of impeding lower-cost competition and the result of driving up the average price for memantine. See Tr. 286:18–287:9 (Saunders), 376:3–17 (Berndt). This conflicts with the notion that patients should not be switched off of a drug that is working. Tr. 58:5–15 (Lah); Lah Decl. (PX85) ¶ 25; Polivka-West Dep. 90:2–7.

118. [redacted] Tr. 232:21–233:20 (Saunders); Tr. 411:24–412:5; 413:23–414:23; 415:12–416:5 (Berndt). Forest seeks [redacted] greater retention of sales after generic entry than it would have had absent a forced switch. TR:

233:21-23 (Saunders). As Dr. Berndt testified, [redacted] Tr. 411:12-412:20 (Berndt).

119. Defendants have referenced several pro-competitive for the limited distribution in conjunction with this litigation: [redacted] savings in inventory costs; savings due to greater "focus" and a reduction in manufacturing costs; benefits from "focus" on newer innovations; and distribution and other supply chain-related savings. Meury Hr'g 570:12-20; Meury Decl. (DX720) ¶ 14; Saunders Dep. 222:10-21; Saunders Dep. 66:13-17; Solomon Dep. 64:4-13, 203:7-17, 203:17-204:2; Meury Hr'g 569:17-21; Meury IH Tr. 270:11-272:24.

120. However, Defendants have not quantified most of the savings resulting from limiting distribution of Namenda IR. Tr. 234:25-235:4 (Saunders); Tr. 416:10-20 (Berndt). Defendants' economic expert has also not quantified any savings from discontinuing the widespread availability of Namenda IR. Cremieux Dep. 238:14-241:21.

121. Defendants' two senior management witnesses, Saunders and Meury, did not testify that the purported savings from the hard switch were considered when the strategy was adopted, nor do these explanations appear elsewhere in the documents produced by Defendants.

122. [redacted] Tr. 416:6-20 (Berndt); Berndt Decl. (PX64) ¶ 80-82 (pro-competitive rationales proffered by Defendants, including "focus," are not credible).

123. Presumably in part because of its announced discontinuance, [redacted] which addresses any concern that selling multiple drugs for the same indication reduces "focus." Tr. 221:5-9 (Saunders). While the oral solution is nominally on the market, Defendants do not promote it, and physicians do not prescribe it. Tr. 245:13-14 (Saunders); Tr. 58:16-59:1 (Lah); Tr. 732:9-12 (Reisberg); Jacobs Dep. 104:9-15; Rovner Dep. 102:18-20.

124. Since the launch of Namenda XR in mid-2013, [redacted] Tr. 605:16-606:4 (Meury). [redacted] Tr. 606:14-22 (Meury).Sales reps are told to promote Namenda XR, not IR. Tr. 606:14-22 (Meury). [redacted] Tr. 606:10-13 (Meury) [redacted].

125. Continuing to keep IR tablets available is highly unlikely to have any impact on Defendants incentive to innovate. Forest launched 8-9 new drugs in new therapeutic areas in the last five years without discontinuing or limiting distribution of any other drug. Tr. 894:3-895:5 (Cremieux).

VI. Effect of the Anti-Competitive Conduct

A. Damage to Competition

126. As found above, Namenda IR, Namenda XR, and in the future any AB-rated generics that may enter constitute the relevant product market, i.e., the memantine market. Tr.336:14-16 (Berndt). As found above, Defendants currently have all of the sales in that market. Patents and other regulatory requirements prevent potential competitors from entering that market. The first generic versions of Namenda IR are expected to enter the market in July 2015.

127. By implementing the limited distribution, Defendants game the generic substitution laws and prevent pharmacists from offering patients taking Namenda a lower-priced generic. As a result of the hard switch strategy, the pharmacist would need to contact the doctor in order to obtain approval for generic substitution. Tr. 409:12-23 (Berndt); Berndt Decl. (PX64) ¶ 50. If pharmacists are not permitted to dispense a lower-priced generic instead of the brand without needing to get a new prescription from a doctor, generics are unlikely to be able to make substantial sales. Stitt Decl. (PX122) ¶ 22; Lah Decl. (PX85) ¶ 32; Berndt Decl. (PX64) ¶ 50; Tr. 380:19-381:7, 381:11-15 (Berndt).

128. Generic products are typically not marketed to physicians or patients. Harper Decl. (PX496) ¶ 11; Tr. 62:24-63:1 (Lah); Jacobs Dep. 203:7-18 ("Q. What about from generic drug companies, do you get any marketing information or pens from those firms? . . . A. I don't remember ever getting—I don't know anything about generic companies honestly, never heard of one. Q. You can't name a single generic company? A. Not at all."); Tr. 759:8-25 (Kohrman) (no sales calls from generic manufacturers other than branded generics several years after entry).

129. For example, Mylan does not have any direct relationship with patients, does not talk to doctors, and does not do direct-to-consumer advertising. Moreover, "generic products . . . most efficiently will achieve sales through AB-rated substitution for the branded product at the pharmacy level." Tr. 327:1-14 (Harper). Generics compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete. Tr. 299:24-300:3, 327:15-328:4 (Harper). In addition, "because the generic [firm] promoting the product would have no way to ensure that its generic product, rather than an AB-rated generic made by one

of its competitors, would be substituted for the brand by pharmacists, a substantial investment in marketing a generic product to physicians would not make sense as a practical matter." Tr. 328:5-11 (Harper).

130. Generic manufacturers do not generally market to health plans. As MVP's representative testified:

> Q. In your experience, do generic drug manufacturers engage in marketing?
>
> A. Not to the—I'm going to just answer no. But they may in journals put [advertisements] out. But I have never had a generic manufacturer call on me at the health plan. And I could have brand manufacturers coming in every day to sell their drugs.
>
> So I would say generic manufacturers don't market, and the—probably the most—I mean, the reason for that would be simple. Because if you're one of three and you get somebody to write a prescription and you didn't—and not indicate dispense as written, the benefit isn't necessarily going to accrue to you. You're only going to get, if there's three people out there, maybe a third of that business. So just the motivation behind marketing a generic product is limited when compared to a brand product.

Tr.117:5-19 (Stitt).

131. Generic manufacturers compete by selling products at a significant discount relative to their branded equivalents, and that discount typically increases as additional generic versions of a branded product enter the market. Tr. 376:12-17

(Berndt); Harper Decl. (PX496) ¶ 5; see Berndt Decl. (PX64) ¶ 17.

132. Price competition at the pharmacy, facilitated by state substitution laws, is the principal means by which generics are able to compete in the United States. See Berndt Decl. (PX64) ¶¶ 10, 22, 44-46; Stitt Decl. (PX122) ¶¶ 21-22; Tr. 116:4-117:4 (Stitt); Harper Decl. (PX496) ¶ 10; Tr. 299:12-23 (Harper); see also Tr. 409:6-11 (Berndt); Tr. 114:21-115:3 (Stitt); Tr. 897:3-22 (Cremieux); Brief for Intellectual Prop. & Antitrust Law Professors as Amici Curiae at 14, Mylan Pharms., Inc., v. Warner Chilcott Pub. Ltd. Co., 2:12-cv-03824 (E.D. Pa. May 7, 2014) (PX5) ("Under Hatch-Waxman and state substitution laws, generics can only compete cost-effectively through substitution on the new or old branded-drug version."). Generic Namenda will not be AB-rated to Namenda XR and generics will not be automatically substituted for Namenda XR (after entry in 2015) under New York's mandatory substitution laws. Tr. 115:19-25 (Stitt).

133. Non-AB-rated generic drugs, such as generic memantine, cannot compete effectively for sales of a branded drug in the same class, such as Namenda XR, even if the price of

the generics is much lower than the brand. For example, imposing utilization plans to shift people from Lipitor—the "biggest [drug] in history"—to generic simvastatin, a non-AB-rated generic in the same statin class, only resulted in 30% of patients switching from Lipitor to simvastatin. Tr. 815:13-817:5 (Kolassa).

134. If Defendants are permitted to execute the limited distribution, they would achieve significantly higher levels of conversion from Namenda IR to Namenda XR than they would have achieved absent the forced switch. Tr. 218:12-16 (Saunders). Before October 2013, Forest predicted that it could switch approximately [redacted] of Namenda IR patients to Namenda XR without a hard switch, but Defendants' hard switch strategy is expected to result in [redacted] of Namenda IR patients switching to XR prior to generic entry. Tr. 217:25-219:3 (Saunders); Presentation titled "Namenda IR & XR Conversion Plan" (PX31) at 31; Presentation discussing "Namenda Disruption Scenarios" (PX45) at 1; Meury email with subject line reading "Re: Namenda Financials" (PX46) at FRX-NY-01565787.

135. Forest has predicted that forcing a hard switch from Namenda IR to XR will generate over [redacted] in

additional sales of Namenda XR than it would have absent a hard switch. Tr. 221:10-15 (Saunders).

136. The limited distribution "is likely to have a significant impact on potential generic competition," in that "[d]iscontinuing Namenda [IR] in late 2014 and shifting the market to Namenda XR ensures that by the time generic entry occurs in July 2015, there will be few to no prescriptions of Namenda left in the market." Tr. 326:3-16 (Harper); Tr. 124:21-125:9 (Stitt) (because Namenda is the only drug in the "particular cascade" of drugs used to treat Alzheimer's, "prescribers will be forced essentially to switch to the XR product."). This decreases the sales opportunities available to generic manufacturers because few patients are left on Namenda IR who can switch to generics under state substitution laws. Tr. 380:15-381:10; 409:12-23 (Berndt).

137. Forest internally predicted that, absent the forced switch, it would only be able to switch [redacted] of Namenda IR prescriptions to Namenda XR prior to generic entry. Tr. 217:25-218:5 (Saunders). If [redacted] of patients switched to Namenda XR, then generic substitution laws would cause about 90% of the remaining [redacted] of patients still taking Namenda IR to be switched

to generics within a few months of generic entry. Tr. 217:25-218:16 (Saunders).

138. Meury stated to investors that perhaps 5-30% or more of patients taking Namenda XR might switch back from Namenda XR to generic memantine at some point after generic entry, a process occasionally referred to as "erosion" or a "reverse commute." April 29, 2014 transcript of earnings call (PX366) at 12-13; Tr. 88:2-8 (Lah), 223:13-22 (Saunders), 390:9-392:17 (Berndt), discussing PX366 ("Q. Okay. Now what did you take way from this exchange? A. I take it that by April of this year, Forest had conducted a fair bit of research, its marketing folks had done that; that they came up with a wide range of estimates, and that Meury and Saunders believed the range of 5-30 percent is a reasonable range. But notably it's much, much less than 100 percent or the 90 percent you would get from a conventional launch."). Meury represented to investors in the April call that generic erosion would not be on the high side of that estimate. April 29, 2014 transcript of earnings call (PX366) at 13. That is, 63% of the market would typically be generic.

139. As a result of the limited distribution, Defendants will be able to maintain their monopoly share of the market for memantine for longer than they would have otherwise. Defendants predicted that they would have had a [redacted] share of the market and generics would have had a [redacted] share but for the hard switch. Instead, under the hard switch scenario, the results are essentially inverted. In 2016, Defendants are likely to achieve an [redacted] share of the market and generics are likely to achieve a [redacted] share. The following graphic, PX580, prepared by the State, is based on data from Defendants' files and reflects this market effect:

140. Dr. Hausman, Defendants' economic expert, corroborated [redacted] that as a result of the hard switch, market shares would dramatically change. Tr. 688:7-11 (Hausman). He did not dispute that with the hard switch, a large number of the patients that would have gone on to generics would instead end up on Namenda XR. Tr. 692:12-16 (Hausman).

141. Mylan predicted, in early January 2014, that prescriptions being written for XR would reduce the market for IR by [redacted]. Tr. 300:6-303:17 (Harper); Mylan Namenda sales forecast, January 2014 (PX142). Following Forest's announcement that it would discontinue IR in August, the generic manufacturer revised its estimate of IR market share loss to [redacted]. Tr. 303:18-304:23, 305:7-11 (Harper); Mylan Namenda sales forecast, (PX145) (April 2014). After doing a "deeper dive" in the summer of 2014, the generic manufacturer further revised its estimate, estimating that the forced switch would reduce the Namenda IR market by [redacted]. Tr. 310:14-25 (Harper); Mylan Namenda sales forecast (PX148) (July 2014). Mylan's January forecasts predict that Mylan's revenue from generic Namenda IR will stabilize around [redacted] per quarter. Mylan Namenda sales forecast, (PX142) (Jan. 2014). By contrast, Mylan's July forecasts predict that Mylan's revenue from generic Namenda IR will stabilize at [redacted] per quarter. Mylan Namenda sales forecast, July 2014 (PX148). Defendants' CEO made a similar projection as to the effectiveness of the forced switch. Saunders Dep. 117:16-118:2; Tr. 117:5-25 (Saunders).

142. To date, about 50% of existing patients have converted from Namenda IR to Namenda XR in anticipation of the

lack of availability of Namenda IR. Press Release, Forest Labs., Inc., "Forest Laboratories Announces Intention to Continue Marketing both NAMENDA® Tablets and Once-Daily Namenda XR into the Fall of 2014" (PX41) (June 10, 2014).

143. As found above, several factors are likely to inhibit switching from Namenda XR to generic memantine once it becomes available in the market. Physicians and caregivers are reluctant to disrupt patients' medical routines without a medical reason to do so. Tr. 131:8-133:22 (Stitt), 508:1-3, 541:21-542:4 (Kane).

144. In addition, health plans are reluctant to pressure patients to switch from a drug that they are already taking, a rule that applies especially powerfully in the case of vulnerable patients such as those with Alzheimer's. Stitt Decl. (PX122) ¶¶ 45, 47; April 28, 2014 earnings call (PX82) at 13.

145. MVP, the New York health plan, for example, is unlikely to try to move patients taking Namenda XR to Namenda IR because of the challenges of moving a patient off a drug when he is doing well on the drug he is taking. Tr. 134:12-139:16 (Stitt); Stitt Decl. (PX122) ¶ 45.

146. This reduction in the market opportunity for generics, from an estimated [redacted] prescriptions down to [redacted] within a few months, and further to [redacted] in six to eight months, is a substantial harm to competition. Tr. 380:15-381:15 (Berndt).

147. The Defendants' expert and fact witness predict that third party payors and the other intermediaries discussed at length above will intervene to thwart Defendants' attempts to limit generic memantine's drive into the market. See generally Kolassa Decl. (DX821) and this Opinion's Findings of Fact ("FOF") § II, E. [redacted] First, as sophisticated market participants with extensive experience as both branded and generic manufacturers of drugs, Defendants are unlikely to have adopted the limited distribution strategy, [redacted] and incurring the legal expense and reputational costs associated with this action, [redacted] Second, Dr. Kolassa's exhaustive analysis of the cost pressures faced by manufactures generalized across

different drug markets. Neither he nor the Defendants analogized between the memantine market and the drug markets in which the eight other examples of "hard switches" occurred. As found above, this market features a unique unsubstitutable product and patients that are extremely sensitive to changes in routine. It is these specific characteristics that make limited distribution so harmful to patients and to competition, and therefore so enticing a strategy upon which Defendants hope to profit.

B. Damage to Consumers

148. Consumers benefit from the lower prices of generic drugs. Tr. 803:6-8 (Kolassa).

149. Once patients have switched to Namenda XR, it is very unlikely that most of them will switch to generic Namenda IR. In April 2014, Forest's head of sales told investors that perhaps 5-30% of patients taking Namenda XR might switch from Namenda XR to generic Namenda at some point after generic entry. Yoon Decl. Ex. 5 at 13.

150. This reduction in the market opportunity for generics, [redacted] of the market going to

generics without the forced switch, to only about 5-30% with the forced switch, not only substantially harms competition but affects the cost of memantine to consumers. Tr. 336:9-337:8 (Berndt). Based on Defendants' own data, Dr. Berndt testified that health plans will pay at least [redacted] more and patients will pay [redacted] more for memantine because of the actions challenged in this litigation. Berndt Decl. ¶¶ 61-64. Dr. Berndt's testimony was credible and substantially not impeached.

151. Physicians are reluctant to disrupt patients' medical routines without a medical reason to do so. Lah Decl. (PX85) ¶ 25 (won't switch a patient who is stable and doing well). One of Defendants' medical expert testified that he continues his patients' current prescription even when he would not prescribe the drug himself to patients not already taking it. Jacobs Dep. 81:14-82:11 ("[I]f they are on a drug and it is working for them and there was no reason to change it, I wouldn't change it."). After patients have been forced to bear a change in routine by switching to Namenda XR, physicians are reluctant to have their patients switch again. Lah Decl. (PX85) ¶ 11; Stitt Decl. (PX122) ¶ 47 ("[P]hysicians are also reluctant

to switch patients to a different drug when the patient is already doing well on the current drug they are taking.").

152. According to Saunders, this "behavioral change" inhibits switching from Namenda XR back to generic memantine. Declaration of Saami Zain, dated September 24, 2014 Ex. 1; Saunders Dep. at 204-05, annexed to Yoon Decl. as Ex. 12.

153. Defendants' forced switch will also result in dramatically higher drug costs for insurers and patients, who might otherwise have chosen the less expensive generic. Stitt Decl. (PX122) ¶ 36 (Defendants' forced switch will lead MVP to "incur substantially higher costs for its member[s]" and hurt patients, who would have higher co-pays for the brand); Tr. 411:24-412:20 (Berndt) & William Meury email and attachment re: Namenda Transition Plan 1.ppt (PX339) (showing increased profits); Tr. 405:16-406:1 (Berndt); Berndt Decl. Figure 4 and accompanying text (showing harm to patients and plans). As Stitt, an executive at MVP, explained:

> I believe that if Actavis is permitted to accomplish the "forced switch" of patients from Namenda to Namenda XR, it will hurt patients, impose significant costs on MVP, and harm the economics of the health care delivery system.

PX122 (Stitt Decl.) ¶ 56.

154. Alzheimer's patients who are Namenda's users (those with moderate to late stages of the disease) are an especially vulnerable group of patients. Lah Decl. (PX85) ¶ 24; Stitt Decl. (PX122) ¶ 45; Tr. 379:8-14; 383:12-14 (Berndt); Forest Laboratories F4Q 2014 Earnings Call Transcript (PX82). Given Alzheimer's patients' vulnerability, "[a]ny small change in medication raises the risk of an adverse event" and "[e]ven a small change in a patient's condition can require him or her to be moved to a care facility." Lah Decl. (PX85) ¶ 24; Tr. 58:5-15 (Lah).

155. Physicians can also be reluctant to switch medications because the patients and others, such as their caretakers, must be educated on how the new medication is taken. Stitt Decl. ¶ 47; Polivka-West Dep. 72:23-73:4.

156. Further, the forced switch could actually result in a portion of these vulnerable Alzheimer's patients having to switch medications (and face the risks of adverse events) twice: once because Namenda XR will be the only product available to

patients; and again because some small number of patients may switch back to the generic Namenda IR once it is available.

157. Defendants' surveys show that many physicians, caregivers, and pharmacists are concerned about potential harm to patients from the forced switch. When presented with the possibility that Defendants would restrict the availability of Namenda IR, physician responses to the survey included statements like "terrible," "how awful," "horrible," "what kind of game is the drug company playing?," "It puts an undue burden on us and would anger me," and "Is this legal?" Physician survey responses concerning limited distribution plan (PX311) at 1; Physician survey responses concerning limited distribution plan (PX298) at 5, 14. Other physicians specifically complained of the reduction in choice, stating that they "would be frustrated that a good therapy is no longer available" (Physician survey responses concerning limited distribution plan (PX311) at 3; Physician survey responses concerning discontinuation plan (PX299) at 4; Physician survey responses concerning limited distribution plan (PX298) at 22, that they "would like the choice to be decided between myself and my patients," (Physician survey responses concerning limited distribution plan (PX311) at 3) and that they suspect Forest "is

manipulating the market to shift to XR product in anticipation of generic availability." Physician survey responses concerning limited distribution plan (PX298) at 22.

158. Defendants' economic expert testified that, based on actual decisions made in the market, approximately [redacted] of physicians prefer Namenda IR and approximately [redacted] prefer Namenda XR. Tr. 716: 19-25 (Hausman).

159. Defendants' surveys also asked doctors and caregivers whether the discontinuation of Namenda IR would be "acceptable," as opposed to a word with a more positive connotation, such as "desirable." Tr. 503:10-16 ("To be acceptable, they would accept it. They wouldn't challenge it."). Even using Defendants own surveys and methodology, 21% of the caregivers surveyed by the Defendants did not find discontinuation of Namenda IR to be acceptable. The reasons provided by such caregivers include "patient used to it," "keep things the same for now," "he likes having his schedule stay the same," "doing well [with] it, no reason [to] change," and "I prefer not to change up her medication at this point." Caregiver survey responses concerning preference for IR versus XR (PX304) at 2, 3, 9, 10, 15.

160. Defendants' documents reflect their expectation that "[p]rescribers, patients, caregivers may be confused or dissatisfied with either withdrawal or limited distribution scenario and may choose to discontinue Namenda treatment." Zain Decl. Ex. 31 at 4. Consequently, Forest projected that somewhere between [redacted] of all Namenda patients would not switch to Namenda XR and instead cease memantine treatment entirely. Zain Decl. Ex. 30 at 31; Zain Decl. Ex. 44 at 1; Zain Decl. Ex. 45 at FRX-NY-01565787.

161. If Defendants are allowed to implement their hard switch strategy, harm to consumers, and the corresponding gain to Forest, would be approximately [redacted] based on Defendants' expert's data. Tr. 405:5-406:6 (Berndt). Consumers would bear approximately [redacted] in additional co-payment costs and [redacted] in third party payor costs. Tr. 405:5-406:6 (Berndt).

162. Based upon the facts found above, the public interest would be served by an injunction. Defendants are entitled to a just return on their investment in Namenda IR, but having enjoyed that return for over a decade, the law now requires them to allow generic competitors a fair opportunity to

compete using state substitution laws. Tr. 417:17-418:14 (Berndt) (rejecting Defendant's "free-riding" argument, and explaining quid-pro-quo of patent exclusivity followed by generic entry).

163. The facts with respect to the harm to competition, to the consumers and consequently the state, the ultimate payor of certain costs, have been found above.

164. Aside from the effect resulting from federal and state legislation, the Hatch-Waxman Act and the state substitution laws, the Defendants have not established any harm resulting from the continued sale of Namenda IR.

165. [redacted]

166. The continuation of sales of Namenda IR adds choice to physicians, patients' health plans and insurers and

constitutes a soft switch which has been the industry practice when introducing a new drug.

167. The Defendants have not presented any evidence to establish material economic harm resulting from the continued sale of Namenda IR after the introduction of Namenda XR, other than that which is anticipated upon the entry of generic competition resulting from the relevant legislation.

Conclusions of Law

VII. The Preliminary Injunction Standard

The general purpose of a preliminary injunction is to avoid irreparable injury to the movant and to preserve the court's power to render a meaningful decision after a trial on the merits. See WarnerVision Entm't Inc. v. Empire of Carolina, Inc., 101 F.3d 259, 261 (2d Cir. 1996); see also 11A Charles A. Wright & Arthur R. Miller, Fed. Prac. & Proc. Civ., § 2947 (3d ed.).

A party seeking a preliminary injunction must establish: (1) either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in favor of the moving party; (2) irreparable harm; and (3) that issuance of the injunction would be in the public interest. See Oneida Nation of N.Y. v. Cuomo, 645 F.3d 154, 164 (2d Cir. 2011) (internal quotations and citations omitted); Red Earth LLC v. United States, 657 F.3d 138, 143 (2d Cir. 2011).

With respect to the likelihood of success element, a movant must satisfy a higher standard where: "(i) an injunction will alter, rather than maintain, the status quo, or (ii) an injunction will provide the movant with substantially all the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits." Id. at 33-34. Under this higher standard, a movant must show a "clear" or "substantial" likelihood of success on the merits or make a "clear or substantial showing of sufficiently serious questions of merits in their favor." See Wright v. New York State Dep't of Corr. & Cmty. Supervision, 568 F. App'x 53, 55 (2d Cir. 2014) quoting Tom Doherty, 60 F.3d at 33-34 (discussing the heighted standard with respect to likelihood of success on the merits); Jolly v. Coughlin, 76 F.3d 468, 473 (2d Cir. 1996) (same); Suthers v. Amgen, Inc., 372 F. Supp. 2d 416, 425 (S.D.N.Y. 2005) (discussing the heighted standard with respect to substantial question analysis); Shred-It Am., Inc. v. Haley Sales Inc., 01-cv-0041E, 2001 WL 209906, at *1 (W.D.N.Y. Feb. 26, 2001) (same). The movant must also make a "strong" showing of irreparable harm. Doe v. New York University, 666 F.2d 761, 773 (2d Cir. 1981). Defendants urge that the heightened standard as described in Tom Doherty be applied in this case. Defs.' Mem. in Opp'n 13-15.

The instant motion does not require the heightened standard set out in Tom Doherty. While, "[t]he distinction between mandatory and prohibitory injunctions is not without ambiguities or critics . . . [a] preliminary injunction is usually prohibitory, [i.e., forbids or restrains an act,] and seeks generally only to maintain the status quo pending a trial on the merits." Louis Vuitton Malletier v. Dooney & Bourke, Inc., 454 F.3d 108, 114 (2d Cir. 2006) (internal quotations omitted) citing Tom Doherty, 60 F.3d at 34 and Black's Law Dictionary 788 (7th ed.1999). The State is seeking an injunction barring Defendants from altering their current Namenda IR sales and distribution strategy pending a final resolution of this case. AC ¶ d. The requested interim relief would maintain the status quo, i.e., continue Defendants' current Namenda IR sales and distribution activities in order to preserve the Court's power to make a final determination regarding the legality of Defendants' proposed new course of action. The authorities Defendants cite in support of the higher standard are inapposite, as those pertain to injunctions that would alter rather than perpetuate the status quo. See e.g., Lincoln Cercpac v. Health and Hospitals Corp., 920 F.Supp. 488, 494 (S.D.N.Y. 1996) (holding that an injunction to re-open

an already-closed hospital would be mandatory rather than prohibitive, since it would upset the status quo); Cacchillo v. Insmed, Inc., 638 F.3d 401, 405 (2d Cir. 2011) (holding that an injunction requiring a company to provide a document that it had, up to that point, refused to provide is mandatory rather than prohibitive); SEC v. Unifund SAL, 910 F.2d 1028, 1039 (2d Cir. 1990) (holding that a prohibition against violating securities laws in the future is mandatory rather than prohibitive); Union Cosmetic Castle, Inc. v. Amorepacific Cosmetics USA, Inc., 454 F. Supp. 2d 62, 68 (E.D.N.Y. 2006) (holding that an injunction requiring a company to re-establish a severed business relationship is mandatory rather than prohibitive); Vantico Holdings v. Apollo Mgmt., LP, 247 F. Supp. 2d 437, 451 (S.D.N.Y. 2003) (holding that an injunction requiring a party to alter the way it votes is mandatory rather than prohibitive).

The second aspect of the Tom Doherty heightened standard is also inapplicable. A preliminary injunction would not provide the State with substantially all of the final relief it seeks in this case. The State seeks a permanent injunction and civil penalties for current violations of New York law and seeks to recover damages caused by Defendants' "misleading

announcements of the timing and scope of their discontinuation of Namenda IR." Pl.'s Mem. in Supp't 20; AC ¶ c. Moreover, the preliminary injunction would only bar Defendants from altering current Namenda IR distribution until a final adjudication of this case is completed.

Since a heightened mandatory injunction standard does not apply in this case, the State may show the following to succeed on its motion for a preliminary injunction: (1) a sufficiently serious question going to the merits of its claims to make them fair ground for litigation; (2) irreparable harm in the absence of the preliminary injunction; (3) a balance of the hardships tipping decidedly in its favor; and (4) that issuance of the injunction would be in the public interest. See Oneida, 645 F.3d at 164.

VIII. Substantial Questions of Antitrust Violations Exist

The State has presented facts as set forth above to support its claims of violations of Sections 1 and 2 of the Sherman Act, and of New York State's Donnelly Act.